

U.S. Patent Application Serial No. **10/541,746**  
Amendment filed January 20, 2010  
Reply to OA dated October 26, 2009

**REMARKS**

Claims 1-37 are pending in this application. Claims 3, 5 and 7 are canceled herein without prejudice or disclaimer, and claims 1, 2, 4, 6, 8, 19 and 37 are amended herein. Upon entry of this amendment, claims 1, 2, 4, 6 and 8-37 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is detailed below.

**Claims 1-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415); an English machine translation of Katagiri et al. (JP 06-214197) was used. (Office action page 2)**

**Claims 19-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415); an English machine translation of Katagiri et al. (JP 06-214197) was used. (Office action page 5)**

**Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and**

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**further in view of Valiant, JR. et al. (US 2002/0102415). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 6)**

**Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Hayashi et al. (US 6,503,632). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 7)**

**Claims 29-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Walther et al. (US 6,379,004). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 8)**

**Claims 31-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Turek et al. (US 2002/0137811). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 9)**

**Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 19 above, and**

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**further in view of Niwa et al. (US 5,516,467). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 10)**

**Claim 37 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415); an English machine translation of Katagiri et al. (JP 06-214197) was used. (Office action page 11)**

Reconsideration of the rejections is respectfully requested in view of the amendments to the claims. Independent claims 1, 19 and 37 have each been amended to limit the “pyrrolidone derivative in which a polymerizable group is a vinylidene group that includes a carbon atom of a pyrrolidone ring” to be “selected from the group consisting of 1-alkyl-3-methylene-2-pyrrolidone, 1-alkyl-5-methylene-2-pyrrolidone, and 5-alkyl-3-methylene-2-pyrrolidone,” as supported by original claims 3, 5 and 7. The dependent claims have been amended for proper dependency and antecedent basis.

Shibata et al. discloses that N-MMP has a superior copolymerizability with other monomers. However, the target of the copolymerization with N-MMP is an alkyl acrylate or an alkyl metacrylate; the N-MMP is highly copolymerizable with these monomers, leading to a well crosslinked product (column 2, line 25-26). Therefore, there is no motivation in this disclosure for copolymerizing N-MMP with a silicone compound, as in the present invention.

Therefore, although the Dk value of the optical lens material obtained by the present invention becomes more than 51, the Dk value of the optical lens material obtained by Shibata et al. becomes absolutely lower, 23-43.

**Further, Shibata et al. aims to obtain a hydro gel in which water content (WC) exceeds over 55.8% by weight.** Therefore, it can be understood that **Shibata et al. uses N-MMP for the purpose of increasing copolymerizability to an alkyl acrylate or alkyl metacrylate, which are added for the purpose of increasing stability of the lens material.** That is, it can be understood that N-MMP is used as "an auxiliary monomer" to educe the advantage of N-VP and is not used as an alternative to N-VP. The optical lens material of Shibata et al. is manufactured based on a quite different idea from the present invention.

Table.1 Comparison of the present invention and Shibata et al

	the present invention	Shibata et al
oxygen permeability (Dk)	more than 51	23-43
Water Content (WC)	less than 55%	more than 55.8%

In regard to Baba et al.

Baba et al. discloses that a contact lens that has superior surface wettability and kinetic property is obtained by exactly controlling the amount of monomer and crosslinking agent for the purpose of preparing a silicone hydro gel lens which essentially contains N-VP.

In the present invention, the residual monomer can be decreased drastically with keeping properties of N-VP such as superior hydrophilic property and wettability for the purpose of making

a silicone hydro gel lens by using an N-MMP as an alternative compound to N-VP (Table 1-3, Example 1, Table 6-7, 11-12, Example 17, and Comparative Example 2, etc.).

The Examiner states the above properties are easily predictable from Shibata et al. and Baba et al. Although Shibata et al. discloses superior copolymerizability between N-MMP and alkyl metacrylate, there is no specific Example in Shibata et al. about good copolymerizability or the elution amount of polymer. As described in Table 4 of the present specification, it is clearly confirmed that the amount of elution of unpolymerized polymer in the system of using N-VP (Comparative Ex. 1) is larger than the system of using 1,3-MMP (Ex. 1). This result means that it is very important to reduce the amount of elution of unpolymerized polymer or oligomer from the finished contact lens to prepare a high safety ocular lens, and not only to reduce the amount of elution of unpolymerized monomer.

Table 2. Comparison of the present invention and Baba et al

	Example 1 of the present invention	Comparative Example 1 of the present invention (corresponding to Baba et al)
residual ratio of monomer (%)	0.2	1.0
elution amount of TOC (ppmC, 14 days after sterilization)	4.8	11.8

In this manner, the effects of simplifying the step of elution treatment to decrease the residual monomer, to reduce the quantity of polymer elution after the sterilization and to obtain a contact lens which has high safety property are industry applicable and are beneficial effects.

For the purpose of making a silicone hydro gel lens, the fact that the above effects in manufacturing result from using a specific combination of monomers, that is silicone macromer (A) and specific kinds of N-MMP (B), is not taught or suggested by Baba et al.

Further, the optical lens material obtained by the present invention has excellent lubricity/easy lubricating property and it is excellent in surface wettability. These properties are clearly understood by comparing Example 17 and Comparative Example 2 (see Table 3, below). The results of feeling test and Contact angle, which become reference marks of lubricity/easy lubricating property, are same level but the result of tensile modulus, which is a reference mark of flexibility of the present invention, becomes absolutely lower than Baba et al. It is clear that the optical lens material of the present invention can provide the contact lens which has high safety and good wearing feeling.

Table 3. Comparison of the present invention and Baba et al  
(material characteristics, from Table 11 and 12 of the present  
invention)

	Example 17 of the present invention	Comparative Example 2 of the present invention (corresponding to Baba et al)
composition		
TRIS	25	25
macromonomer A	25	25
DMAA	12.5	12.5
N-MMP	37.5	-
NVP	-	37.5
feeling test	A	A
contact angle	22	22.0
tensile modulus (MPa)	0.23	0.5

As shown in the above Table 3, the superior effects of the present invention are never obtained by combining compounds of Examples of Baba et al. Considering all the factors together, the contact lens material that has high safety ability, superior surface property and physical property with low quantity of residual monomer is obtained by using specific kinds of N-MMP as an alternate compound of N-VP, and it is not suggested by any of the cited references. Therefore, these effects

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of the present invention are not seen in the cited references and are unexpected results from Shibata et al. and Baba et al.

In regard to Katagiri et al.

The compound (A) of the present invention has a polydimethylsiloxane structure, and this compound is not disclosed nor suggested in Katagiri et al. A silicone including (metha)acrylate, which is represented by B compound of Katagiri et al., corresponds to the compound (C) of the present invention. Further, a compound which has a polydimethylsiloxane structure is described as an example of "non-aqueous contact lens which does not have hydrophilic compound" in Katagiri et al. However, such a compound having a polydimethylsiloxane structure has poor compatibility with other compounds having high hydrophilic property, such as compound (B) of the present invention, because of the hydrophobic property.

As discussed above, claim 1 has been amended to limit compound (B) to be "selected from the group consisting of 1-alkyl-3-methylene-2-pyrrolidone, 1-alkyl-5-methylene-2-pyrrolidone, and 5-alkyl-3-methylene-2-pyrrolidone," which have high hydrophilic property.

Further, as shown in Comparative Examples 4 and 5 of Table 12 of the present invention, the compatibility with silicone including (metha) acrylate like Katagiri et al. becomes poor in the case of using N-MMP, which has high hydrophilic property, and the resulting transparency becomes poor. In the present invention, homogeneity of the lens is improved (please see the result of transparency of Example 14, shown in Table 11, and the result of transparency of Comparative Example 4, shown in Table 12) and it becomes possible to use a large amount of a silicone-including



compound as an ocular lens material by using polydimethylsiloxane (A), which has specific structure. As a result, transparency of the ocular lens material becomes dramatically improved.

Further, as described in the BACKGROUND ART section of the present specification, the contact lens material of Katagiri et al. being a target has a water content of about 37 to 58 % and an oxygen permeability of about 26 and 35, and it cannot be said that this has adequate oxygen permeability for continuous wearing or for short sleep (please see the following Table 4).

Table 4. Comparison of the present invention and Katagiri et al

	present invention	Katagiri et al.
Water Content (%)	30-52	37-58
oxygen permeability (Dk)	$51 \leq$	$35 \geq$

In Katagiri et al. the effective amount of silicone compound for adding transparency is not over 30%. On the contrary, the effective amount of silicone compound for adding becomes 60% in the present invention. This result is obtained by the effect of urethane bond of compound (A), which has high compatibility with other compounds. In the present invention, it becomes possible to select a composition that can include a large amount of silicone compound, such as compound (A). As a result of this feature, the present invention becomes able to dramatically increase the oxygen permeability. Therefore, the present invention is not suggested by the cited art and these properties, especially oxygen permeability, are an unexpected result over Katagiri et al.

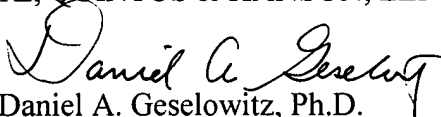
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As described above, the contact lens material of Claim 1 of the present invention, obtained by using specific kind of compound (B) and a compound which has specific polydimethylsiloxane structure, is adequate as a homogeneous and transparent contact lens material. Further, the obtained contact lens material has high oxygen permeability. The pending claims are not obvious over the cited references, taken separately or in combination.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,  
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Enclosure: Request for Continued Examination (RCE)

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